IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, et al. ex rel. BRIAN D. SHANNON, M.D.,
Plaintiffs,

CIVIL ACTION 21-2351

v.

PENN STATE HEALTH ST. JOSEPH REGIONAL HEALTH NETWORK ALSO KNOWN AS ST. JOSEPH MEDICAL CENTER, ST. JOSEPH MEDICAL GROUP, PENN STATE HEALTH, PENN STATE HEALTH MILTON S. HERSHEY MEDICAL CENTER, AND CERNER CORPORATION,
Defendants

MEMORANDUM

SCHMEHL, J. - *JLS* **MARCH 31, 2025**

INTRODUCTION

Relator Brian D. Shannon, M.D. ("Relator"), a former orthopedic surgeon at St. Joseph Medical Center, brought this *qui tam* action on his own behalf and on behalf of the United States of America ("United States") under the federal False Claims Act ("FCA"), 31 U.S.C. § 3729, against Defendants Penn State Health St. Joseph Regional Health Network aka St. Joseph Medical Center, St. Joseph Medical Group, Penn State Health and Penn State Health Milton S. Hershey Medical Center (collectively the "PSH Defendants"). Relator also has asserted claims against Defendant Cerner Corporation ("Cerner") on behalf of himself and 28 states for violation of each jurisdiction's respective state false claims act. Essentially, Relator alleges that the PSH Defendants used Cerner technology to submit false or fraudulent claims for reimbursements to government-funded

healthcare programs including, Medicare, Medicaid, the Federal Employees Health Benefits Program, TRICARE/CHAMPUS, the Veterans Administration and various state governments. Plaintiff has also asserted claims against only the PSH Defendants for retaliation under the FCA, 31 U.S.C. § 3730(h), and the common law of Pennsylvania, as well as state law claims against the PSH Defendants for defamation, invasion of privacy, and breach of contract. Presently before the Court are the motions of the PSH Defendants and Cerner to dismiss all the Counts against them pursuant to Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure. For the reasons that follow, both motions are granted.

STANDARD OF REVIEW

A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of a claim. In reviewing a motion to dismiss, the court accepts as true a complaint's factual allegations and views them in the light most favorable to the plaintiff. *See Phillips v. Cty. of Allegheny*, 515 F.3d 224, 228 (3d. Cir. 2008). Although a complaint need not contain detailed factual allegations to survive a motion to dismiss, it cannot rest on mere labels and conclusions. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). That is, "a formulaic recitation of the elements of a cause of action will not do." *Id.* Accordingly, "[f]actual allegations must be enough to raise a right to relief above the speculative level," *id.*, and be "sufficient to state a claim for relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than the sheer possibility that a defendant has acted unlawfully." *Id.* (quoting *Twombly*, 550 U.S. at 556).

On January 26, 2023, the United States filed a Notice of Election to Decline Intervention. (ECF 17). Relator thereafter made a "supplemental disclosure" to the government and was interviewed by the government. (ECF 63). Despite having received this additional information from the Relator, the United States nevertheless informed the Court on September 7, 2023 that it "maintains its decision not to intervene." (ECF 69).

THE SECOND AMENDED COMPLAINT

Plaintiffs' Second Amended Complaint ("SAC"), consists of 128 pages, containing 34 Counts and 766 paragraphs. Therefore, the Court will briefly summarize Relator's allegations.

Relator is a citizen of Colorado. SAC at ¶ 8. He alleges that he "began his employment with St. Joseph Medical Group on August 1, 2018, and his last day at St. Joseph's was January 31, 2020." *Id*. at ¶10. Relator alleges that he was "constructively discharged in November 2019 due to the PSH Defendants' continuing misconduct and retaliation against him after raising numerous compliance issues with the PSH Defendants' administration over the course of his time at St. Joseph Medical Center." *Id*. at ¶ 16.

Defendant Penn State Health St. Joseph Regional Health Network ("SJRHN") also known as St. Joseph Medical Center ("St. Joseph's") is a nonprofit corporation incorporated and existing under the laws of the Commonwealth of Pennsylvania. SAC at ¶ 18. St. Joseph's maintains offices and healthcare facilities, and is a subsidiary of Defendant Penn State Health. *Id*. at ¶ 19. St. Joseph's is a 204-bed

acute care, JCAHO-accredited[1] hospital located in Reading, Pennsylvania *Id*. at ¶ 20. In mid-2015, Catholic Health Initiatives ("CHI") transferred ownership of St. Joseph's to Defendant Penn State Health. *Id*. at ¶ 21. Defendant St. Joseph Medical Group ("SJMG") is a non-profit corporation incorporated and existing under the laws of the Commonwealth of Pennsylvania. *Id*. at ¶ 22. SJMG is a multispecialty medical group, and a subsidiary of Defendant Penn State Health. *Id.* at ¶ 23.

Defendant Penn State Health is a non-profit corporation incorporated and existing under the laws of the Commonwealth of Pennsylvania. *Id*. at ¶ 24. Penn State Health is a multi-hospital health system serving patients and communities across 29 counties in central Pennsylvania. *Id*. at ¶ 25. The Penn State Health system includes Defendant Penn State Health Milton S. Hershey Medical Center, Penn State Children's Hospital, Penn State Cancer Institute, Penn State Health Holy Spirit Medical Center (Camp Hill, Pa.), Defendant Penn State Health St. Joseph Medical Center and more than 3,000 physicians and direct care providers at more than 126 outpatient practices in 94 locations. *Id*. at ¶ 26. Additionally, the system jointly operates various health care providers, including Penn State Health Rehabilitation Hospital, Hershey Outpatient Surgery Center, Hershey Endoscopy Center, Horizon Home Healthcare and the Pennsylvania Psychiatric Institute. *Id*

Defendant Penn State Health Milton S. Hershey Medical Center ("Hershey") is 564-bed medical center doing business in under the laws of the Commonwealth of Pennsylvania. *Id*. at ¶ 27. Hershey is a JCAHO-accredited hospital, and a subsidiary of Defendant Penn State Health. *Id*. at ¶ 28. Hershey is central Pennsylvania's only locally-

[1] A JCAHO facility is a health-care organization that has been accredited by the Joint Commission on Accreditation of Healthcare Organizations.

based academic medical center corporation. *Id*. at ¶ 29 Hershey shares its campus with Penn State Children's Hospital, Penn State Cancer Institute and Penn State College of Medicine. *Id* at ¶ 30. In October 2020, all of the above-identified PSH-related entities (along with other PSH entities) registered with the Commonwealth of Pennsylvania as "owners", allowing them the use of the fictitious name "Penn State Health Medical Group" even though Hershey and SJRHN d/b/a SJMC are hospitals and not medical groups. *Id*.

Defendant Cerner has developed and sold to hospitals nationwide, including those owned and operated by Defendant Penn State Health, a certified electronic healthcare record ("EHR") technology known as Cerner Millennium. *Id*. at ¶125. This system "permitted providers to sign, decline and/or alter orders (a key element of computerized physician order entry ("CPOE") and the key element of orders in general)." *Id*. at ¶126. According to the SAC, "PSH abused this function." *Id*. Cerner Millennium "allows ancillary departments to generate physician orders within modules such as PharmNet, Pathnet, and RadNet in an uncertified manner via the departmental ordering conversations. Specifically, the departmental ordering conversations allow creation of backdated orders in violation of federal and state regulations**."** *Id*. at ¶143. According to the SAC**,** Cerner Millennium also "allows transmission of physician orders created in an uncertified manner in modules such as PharmNet, PathNet, and RadNet to other Cerner Millennium modules to co-mingle with physician orders created via certified CPOE. There is no way to distinguish between orders created via certified vs uncertified manner**."** *Id*. at ¶144.

According to the SAC, Cerner Millennium products further allow:

- users to determine if orders created by individuals on behalf of an ordering physician/provider need to be co-

> signed, declined, and/or modified by the ordering physician/provider;
> - the creation of unique accession numbers assigned to diagnostic tests in ancillary departments. These accession numbers help catalog the various datapoints associated with the diagnostic test (e.g., orders, reports, actions/events, etc.); and
> - allow users to scan documents (including signed orders) created outside the EHR system into a patient's electronic medical record.

Id. at ¶145.

As examples of such conduct, the SAC alleges that the PSH Defendants: (1) upcoded into improper magnetic resonance imaging ("MRI") and computerized tomography ("CT") procedures utilizing contrast (*id*. at ¶¶ 200-218); (2) upcoded improper ultrasound injection/aspiration procedures (*id*. at ¶¶ 219-238); (3) the PSH Radiology Department improperly ordered an unnecessary scanogram on both legs of a patient despite Relator ordering only a right leg length X-ray (*id*. at ¶¶ 239-249); (4) improperly billed for "post-discharge" durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS") covered by Medicare Part B when such charges should have been billed as "inpatient" DMEPOS that were covered by Medicare Part A. (*id*. at ¶¶ 234-266); (5) incorrectly re-entered orders for a "2 view" x-ray of a patient's ankle in Relator's name after Relator refused to sign the order because only a single view x-ray was performed and "upon information and belief" resulting in the patient or her insurance being charged for two x-rays. (*id*. at ¶¶ 292-296); (6) identified doctors who were not the Relator as the "ordering provider" on surgical specimen orders, or falsely identified Relator as the "ordering provider" resulting in false charges for a patient who was covered by Medicare, a patient that was covered by a Medicare HMO and a patient that was covered by

Medicaid. (*id.* at ¶¶ 312- 317); and (7) Hershey wrongly invented orders for examination of biopsy specimens that Relator deemed unnecessary, including a fine needle aspiration procedure and additional immunostains on one patient and unnecessary radiation therapy and an XGEVA infusion treatment on a terminal cancer patient covered by Medicare. (*id*. at ¶¶ 318-352).

The SAC also alleges that, "upon [Relator's] information and belief," the PSH Defendants have a financial ownership interest in certain companies such as Berks Medical Equipment that provide DMEPOS to SJMG, SJMC and Hershey, which Relator speculates might be a "potential Stark Act Violation." *Id.* at ¶¶ 267-291. Relator similarly alleges "upon his information and belief" that certain commercial relationships between the PSH Defendants and other healthcare entities relating to the St. Joseph's Medical Office Building are so-called "Stark-Related Entanglements." *Id*. at ¶¶ 353-414. Specifically, Relator alleges that, "[u]pon information and belief," PSH is the controlling entity of "PSH Community Medical Group," and that "the hospital and medical group, and their connected holdings and revenue, [have] become interchangeable." *Id*. at ¶¶ 404-414.

The SAC further alleges that Relator raised concerns about improper ordering of surgical specimens for pathologic review despite Relator's explicit instructions to the operating room not to do so (the "specimen policy"), and that the results of an investigation into his concerns were unsatisfactory. *Id*. at ¶¶ 435-512. During a meeting with the Vice President of Medical Affairs and Chief Medical Officer at St. Joseph's, Relator "specifically mentioned that a PSH employee may report the fraud to the government and Relator raised the possibility of a whistleblower lawsuit." *Id.* at ¶ 452.

During another meeting with the Executive Vice President of PSH, Relator alleges he "mentioned to [the Executive Vice President] that PSH was putting itself in danger of a potential fraud investigation, and mentioned the possibility that a PSH employee may file a *qui tam* action based on the fraud." *Id*. at ¶ 480. In light of his dissatisfaction and the PSH Defendants' refusal to address, cease and/or correct their allegedly illegal schemes, Relator resigned his position. *Id*. at ¶¶ 499-504, 510-511. As a result, Relator alleges that he was "constructively discharged" from his position with the PSH Defendants. *Id*. at ¶¶ 435-512.

Finally, the SAC alleges: 1) that Relator verbally requested that nurses not remove a catheter from a patient and that he canceled the hospital's "Nurse Driven Foley Catheter Removal Protocol" that permitted a nurse to remove the Foley catheter without consulting the treating doctor only to discover the next morning that a nurse removed the catheter because the Cerner EHR system had automatically re-entered the hospital's "Nurse Driven Foley Catheter Removal Protocol" (*id*. at ¶¶ 297-311); (2) that, "[u]pon information and belief, the PSH administration stated that the SJMG physicians were being compensated too much" (*id*. at ¶ 354); and (3) that it is "implausible that St. Joseph's was not using 340B [of the Public Health Service Act] discount pricing for outpatient drugs before July 2020, [when it registered to do so] so it must have been utilizing the 340B pricing [prior to July 2020] from a different, unrelated and unidentified program" (*id*. at ¶¶ 415- 434).

Relator asserts causes of action against the PSH Defendants under three provisions of the FCA: 31 U.S.C. § 3729(a)(1)(A), knowingly presenting a false or fraudulent claim for payment or approval to the government (Count I); § 3729(a)(1)(B),

knowingly making or using false records or statements to get a false or fraudulent claim paid or approved by the government ("Count II); and § 3729(a)(1)(C), conspiring to commit an FCA violation (Count III).

THE FALSE CLAIMS ACT

Because an FCA claim sounds in fraud, the relator must plead fraud with particularity under Federal Rule of Civil Procedure 9(b). *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 195 n.6 (2016); *Foglia v. Renal Ventures Mgmt.*, 754 F. 3d 153, 155 (3d Cir. 2014); Fed. R. Civ. P. 9(b). Rule 9(b) requires a plaintiff to "allege all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where, and how of the events at issue." *United States ex rel. Travis v. Gilead Scis., Inc.*, 596 F. Supp. 3d 522, 535 (E.D. Pa. 2022) (quoting *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 176 (3d Cir. 2019)). "Fed.R.Civ.P. 9(b) requires plaintiffs to plead the circumstances of the alleged fraud with particularity to ensure that defendants are placed on notice of the 'precise misconduct with which they are charged, and to safeguard defendants against spurious charges' of fraud." *Craftmatic Sec. Litig. v. Kraftsow,* 890 F.2d 628, 645 (3d Cir.1989) (quoting *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.,* 742 F.2d 786, 791 (3d Cir.1984).

The FCA imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment" to the government**.** "To state substantive causes of action under §§ 3729(a)(1)(A) and (B), a relator must allege facts showing: (1) the defendant presented a false claim for payment to the United States; (2) the defendant knew the claim was false; (3) the false claim or false statement in

support of the claim was material to the payment decision; and (4) the false claim caused the government to pay the claim." *United States ex rel. Scheer v. Beebe Healthcare*, No. CV 20-6117, 2024 WL 219395, at *5 (E.D. Pa. Jan. 18, 2024) citing *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017). In short, a relator must establish falsity, causation, knowledge, and materiality. *Id*.

In seeking dismissal of the FCA claims against them, the PSH Defendants rely primarily on Relator's failure to satisfy the falsity and materiality elements.

Under the FCA, "[a] false or fraudulent claim may be either factually false or legally false." *United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 94 (3d Cir. 2018). A claim is factually false if the claimant misrepresents what goods or services it provided to the Government. *Id*. A claim is legally false if the claimant "lies about its compliance with a statutory, regulatory, or contractual requirement." *Id*. (quotations and citations omitted). According to Relator, this case involves legally false claims. ECF 85 at p. 6.

The Supreme Court has recognized two categories of legally false claims under the FCA—the "express false certification theory" and the "implied false certification theory." *Escobar*, 579 U.S. at 181. Under the "express false certification" theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds. *See United States ex rel. Quinn v. Omnicare Inc.,* 382 F.3d 432, 441 (3d Cir. 2004). The "implied false certification" theory requires showing that the "defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's

noncompliance with a statutory, regulatory, or contractual requirement." *Escobar*, 579 U.S. at 181. To proceed on the grounds of an implied false certification, the plaintiff must plead sufficient facts to plausibly infer that the "defendant knowingly violated a requirement that the defendant knows is material to the government's payment decision." *Id*. This case involves the implied false certification theory.

In either case, however, "a misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." *Escobar*, 579 U.S. at 192. According to the Supreme Court, "[t]he materiality standard is demanding. The [FCA] is not 'an all-purpose anti-fraud statute,' ... or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.* at 194 (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)). Under the FCA, "the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). "[A] misrepresentation is not material 'merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment ... [or because] the Government would have the option to decline to pay if it knew of the defendant's noncompliance.'" *Petratos*, 855 F.3d at 489 (quoting *Escobar*, 579 U.S. at 194). Instead, "[u]nder any understanding of the concept, materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" *Escobar,* 579 U.S. at 193 (quoting 26 R. Lord, Williston on Contracts § 69:12, p. 549 (4th ed. 2003)). As such, "a material

misrepresentation is one that 'goes to the very essence of the bargain.'" *Id*. (quoting *Escobar*, 579 U.S. at 193 n.5).

Falsity under the Stark Act

Relator first claims the PSH Defendants made legally false claims in connection with submitting claims to the government for payment that violated the Stark Act. Section 1395nn(a)(1) of the Stark Act provides, in pertinent part:

> if a **physician** (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then (A) the **physician** may not make a referral to the entity for the furnishing of designated health services [DHS] for which payment otherwise may be made under this subchapter, and (B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

42 U.S.C. § 1395nn(a)(1). (emphasis added). Under the Stark Act, a physician has a "financial relationship" with an entity if the physician has "an ownership or investment interest in the entity," or "a compensation arrangement" with it. 42 U.S.C. § 1395nn(a)(2). A "compensation arrangement" consists, with certain exceptions not here relevant, of "any arrangement involving any remuneration between a physician ... and an entity ...." 42 U.S.C. § 1395nn(h)(1)(A). "The term 'remuneration' includes any remuneration, directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. § 1395nn(h)(1)(B). The Stark Act defines "referral" as "the request by a physician for the item or service, including the request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by (or under the supervision of) that other physician)." 42 U.S.C. § 1395nn(h)(5)(A).

In short, "[a] prima facie Stark Act violation has three elements: (1) a referral for designated health services, (2) a compensation arrangement (or an ownership or investment interest), and (3) a Medicare claim for the referred services." Bookwalter, 946 F.3d at 169. A Medicare claim that violates the Stark Act is a false claim under the False Claims Act. United States ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88, 94 (3d Cir. 2009). In order to establish a Stark Act violation, a plaintiff must allege that a physician referred a patient for a DHS to an entity in which he or she has a financial relationship, and that an exception is not met. 42 U.S.C. § 1395nn; 42 C.F.R. §§ 411.350 et seq; 411 C.F.R. § 351.

Despite the numerous allegations in the SAC detailing alleged improper activity by the PSH Defendants, nowhere in the SAC does Relator allege that **any physician** has a financial relationship with any entity for a DHS. Nor does the SAC allege that **any physician** has referred any patients to any entity in which the **physician** has a financial relationship. Finally, the SAC does not allege **any** claims were billed improperly to a federal health care program for a DHS. Here, as in *Beebe*, "[t]here is nothing in the [Second] Amended Complaint showing that any referring physician had a financial relationship with [the PSH Defendants] or received compensation for referrals." *Beebe Healthcare*, 2024 WL 219395, at *11. In short, Relator fails entirely to plead any facts from which one could infer a falsity based upon a Stark Law violation that a **physician** referred a patient for a DHS to an entity in which he or she has a financial relationship.

Instead, the SAC alleges that, "upon [Relator's] information and belief,"[2] the PSH Defendants have a financial ownership interest in certain companies such as

[2] Plaintiff's allegations that "[u]pon information and belief" are not permissible given that the SAC lacks specific facts upon which the information and belief is reasonably based. See *State Farm Mut. Auto. Ins.*

Berks Medical Equipment that provide DMEPOS to SJMG, SJMC and Hershey, which Relator speculates might be a "potential Stark Act Violation." *Id.* at ¶¶ 267-291. Relator similarly alleges "upon his information and belief" that certain commercial relationships between the PSH Defendants and other healthcare entities relating to the St. Joseph's Medical Office Building are so-called "Stark-Related Entanglements." *Id*. at ¶¶ 353-414. Specifically, Relator alleges that, "[u]pon information and belief," PSH is the controlling entity of "PSH Community Medical Group," and that "the hospital and medical group, and their connected holdings and revenue, [have] become interchangeable." *Id*. at ¶¶ 404-414. These allegations simply do not satisfy the requirement that a physician must have referred a patient for a DHS to an entity in which he or she has a financial relationship, and that an exception is not met. 42 U.S.C. § 1395nn; 42 C.F.R. §§ 411.350 et seq; 411 C.F.R. § 351.

Relator has also failed to plead with particularity that any false claims were actually presented to the government for payment. A relator "must allege the 'particular detail' of a scheme coupled with 'reliable indicia that lead to a strong inference that claims were actually submitted,'" and "[d]escribing a mere opportunity for fraud will not suffice." *Beebe*, 2024 WL 219395, at *8 quoting *Foglia*, 754 F. 3d at 157-58. It is not enough to "merely describe a private scheme in detail but then allege that claims requesting illegal payments must have been submitted, were likely submitted, or should have been submitted to the Government." *Greenfield*, 880 F. 3d at 98 (quotation and punctuation omitted).

Co. v. Ficchi, 2012 WL 1578247, at *5 (E.D.Pa. May 4, 2012). ("S]uch allegations are permissible "only if the pleading sets forth specific facts upon which the belief is reasonably based.").

The SAC merely alleges that "upon information and belief," a patient or his insurance company were charged for underperformed or unnecessary procedures. Relator does not allege that the insurance companies that were allegedly billed were government healthcare programs such as Medicare or Medicaid or allege any reliable indicia that would lead to a strong inference that any alleged improper orders or records in the EHR ended up actually being submitted by the PSH Defendants to the government for payment. *See United States ex rel. Zaldonis v. Univ. of Pittsburgh Med. Ctr.*, No. 2:19-CV-01220-CCW, 2021 WL 1946661, at *6 (W.D. Pa. May 14, 2021) ("the allegation fails to identify whether the patient was the beneficiary of any government healthcare program, like Medicare or TRICARE, which on its own is fatal to this alleged incident supporting an FCA claim"). Basically, Relator merely **assumes** that the alleged improper orders or records were submitted to the government for payment. However, it is not enough to **assume** that false claims were submitted to the government for payment. *Beebe*, 2024 WL 219395, at *8. Just because an "order" was placed in the "Cerner EHR," which is merely an Electronic Health Record for patient records, does not mean the "order" was billed to any entity in general and to the government in particular. The SAC does not contain any allegations that provide any reliable indicia as to how a false claim would be generated to any payor from a hospital's medical billing system by virtue of the allegations relating to "records" or "orders" in the Cerner EHR.

Materiality under Stark Act

Even if Relator could satisfy the falsity requirement, he has completely failed to plead with any specificity that any misrepresentations made by the PSH Defendants

concerning non-compliance with the Stark Act were **material** to the decision of the government to issue any payments. In fact, Relator does not make a single allegation concerning materiality in Counts I and II of the SAC. It is not until the conspiracy claim in Count III that Relator alleges in conclusory fashion that "[h]ad the United States known that Defendants were violating the federal laws and regulations cited herein, it would not have paid the claims caused by Defendants' fraudulent and illegal practices." SAC at ¶ 528. Relator does not plead that the government would not have paid any claims had it known that the orders were "backdated" or unsigned." Relator's failure to do so dooms his case under the FCA.

In addition, our Court of Appeals in *Petratos* affirmed the district court's grant of a motion to dismiss for failure to state a claim under the FCA, finding that the Realtor had failed to satisfy the materiality requirement because the government had declined to intervene and continued to pay claims after the Relator had filed suit. ("We do not think it appropriate for a private citizen to enforce these regulations through the False Claims Act.") 855 F.3d 481 (3d Cir. 2017) citing *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447 (7th Cir. 2016) (dismissing False Claims Act complaint on materiality grounds because "federal agencies in this case have already examined [the claims] multiple times over and concluded that neither administrative penalties nor termination was warranted" (citations and internal quotation marks omitted)) *See also Polansky v. Exec. Health Res., Inc.*, 422 F. Supp. 3d 916, 938 (E.D. Pa. 2019) ("[T]he Government's actions in this case—declining to intervene and moving for dismissal—are probative of the lack of materiality . . . . Post-*Escobar*, numerous federal courts have found insufficient FCA materiality where the government investigated a relator's allegations but chose not

to intervene or otherwise address the defendant's allegedly improper behavior.); *United States ex rel. Cressman v. Solid Waste Servs.*, Civ. No. 13-5693, 2018 WL 1693349, at *6 (E.D. Pa. Apr. 6, 2018) (granting summary judgment in favor of defendant where the Government's "declination to intervene or take any action against [d]efendant support[ed] the conclusion that it d[id] not consider the regulatory violation or failure to disclose asserted by [p]laintiff to be 'material' "). In the case *sub judice*, the government declined to intervene on two separate occasions and the SAC does not allege that the Government denied payment of any claims based on Relator's allegations.[3]

Falsity under Medicare Benefit Policy Manual

Relator also claims the falsity element has been adequately plead based on the PSH Defendants' alleged violation of the Medicare Benefit Policy Manual ("MBPM"). For example, Relator claims that the PSH Defendants improperly ordered diagnostic tests in violation of Chapter 15 of the MBPM. In the first instance, Relator acknowledges in his own pleading that the requirements for ordering diagnostic tests or pathology services under Chapter 15 of the MBPM, § 80.6 are not applicable to hospital inpatients, such as those tests performed by the PSH Defendants. See SAC at ¶ 176 (quoting MBPM) ("Unless specified, these sections are not applicable in a hospital setting"). In the second instance, Chapter 15 of the MBPM contains an exception that permits a pathologist to order additional tests such as special strains without permission from the treating physician/provider provided that the services are medically necessary, the results of the tests are communicated to and used by the treating physician and the pathologist

[3] Nor have any of the individual states elected to intervene in this action.

documents in his report why additional testing was performed. MBPM, ch. 15, § 80.6.5. Relator does not allege that the elements for the exception were not met.

In addition, the SAC alleges that there was a "standing order" for surgical specimens to be sent to the lab for studies. SAC at ¶ 460. The SAC appears to allege that these "standing orders" are impermissible. See, e.g., SAC at ¶¶ 183-85. Applicable regulations, however, state that a "hospital's standing order policy can be used as a substitute for the individual request by the patient's attending physician" to a hospital pathologist for physician laboratory and pathology services. See MBPM, ch. 12, § 60(C)(4). Therefore, even assuming a standing order did in fact exist, the MBPM specifically sanctions such a procedure.

Relator also alleges that PSH Defendants' pathologists performed microscopic evaluations of specimens even though the Relator had only "ordered" a macroscopic (gross) exam of the specimen. See SAC at ¶¶ 313, 315, 447. Medicare regulations, however, provide that **"[t]he medical staff** and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations." 42 C.F.R. § 482.27(a)(4) (emphasis added). Contrary to Relator's assertions, the applicable regulation uses the term "medical staff" and not "treating physician" or "attending physician." The SAC's allegations that certain microscopic evaluations of specimens may have violated regulations or laws because Relator, as "treating physician," did not allegedly order such evaluations, is not supported by the applicable regulations.

Finally, Relator alleges that the PSH Defendants violated laws or regulations because they processed orders that did not contain the Relator's signature.

See, e.g., SAC at ¶¶ 173-74, 187(c), 212-14, 225, 244, 312. Chapter 15 of the MBPM, at § 80.6.1 provides that "**[n]o signature is required on orders for . . . physician pathology services**" but the physician must clearly document, in the medical record, his or her intent that the test be performed." (emphasis added). Relator does not allege in the SAC that the various patients' records did not include documentation of a physician that any test be performed.

Materiality under the Medicare Benefit Policy Manual

For essentially the same reasons that Relator could not establish materiality under the Stark Act, the Court finds that Relator has failed to establish materiality under the MBPM.

In sum, since Relator's allegations concerning improper orders for diagnostic and pathology testing did not violate any law or regulation, the Relator has failed to satisfy the falsity requirement of the FCA. *See United States ex rel. Ellis v. CVS Health Corp.*, No. CV 16-1582, 2023 WL 3204015, at *4 (E.D. Pa. May 2, 2023) (dismissing FCA claim under legal falsity theory because "it is not clear that any statutory, regulatory, or contractual requirements were violated"). Even if Relator did properly allege a legal falsity theory under the Stark Act or MBPM, for the reasons discussed, *supra*, Relator has also failed to satisfy the materiality element.

With regard to Cerner's motion to dismiss, the claims against Cerner in Counts I and II can be disposed of in summary fashion. Relator claims that "Cerner knowingly provided the PSH Defendants with an EHR system that permitted the PSH Defendants to perform and manage unnecessary, extraneous, and often unsafe, procedures and treatments that would be reimbursed by various insurance programs, including Medicare."

ECF 86 at p. 2. "In doing so, Cerner foreseeably permitted the submission of false claims." *Id*. at p. 6. Specifically, Relator states that:

- The Cerner system permitted providers to sign, decline and/or alter orders (a key element of computerized physician order entry (CPOE) and the key element of orders in general).
- Cerner Millennium allows ancillary departments to generate physician orders within modules such as PharmNet, PathNet, and RadNet in an uncertified manner via the departmental ordering conversations. Specifically, the departmental ordering conversations allow creation of backdated orders in violation of federal and state regulations.
- Cerner Millennium allows transmission of physician orders created in an uncertified manner in modules such as PharmNet, PathNet, and RadNet to other Cerner Millennium modules to co-mingle with physician orders created via certified CPOE. There is no way to distinguish between orders created via certified vs uncertified manner.
- Almost every surgeon present at the meeting raised multiple examples of unnecessary specimens getting sent to the lab without orders or reasons.

Id., citing SAC, ¶¶ 126, 143, 144, 145, 187, 302-306, 505.

However**,** Relator does not name a single Cerner employee or identify a single action or statement by an employee connected to any allegedly fraudulent activity. The SAC completely fails to explain how Cerner itself took any improper actions. The SAC only describes how the **PSH Defendants allegedly used or misused Cerner products.** There are absolutely no allegations about actions, statements, or knowledge by anyone associated with Cerner. Therefore, Counts I and II are also dismissed as to Cerner.

RELATOR'S CONSPIRACY CLAIM UNDER THE FCA

Turning to Plaintiffs' conspiracy claim under the FCA in Count III, the Court finds that because Relator has not stated a claim under the FCA in Counts I or II, his conspiracy claim in Count III also fails. *See United States ex rel. O'Bier v. TidalHealth Nanticoke, Inc.*, No. 21-cv-2123, 2022 WL 264554, at *4 n.4 (3d Cir. Jan. 28, 2022) (relator's conspiracy claim "fails because she has not plausibly alleged any underlying

violation of the False Claim Act"). In addition, "[t]o allege an FCA conspiracy, a Relator must identify co-conspirators and allege a specific agreement to violate the FCA." *Travis*, 596 F. Supp. 3d at 541. Here, Relator does not allege when any alleged conspiracy arose, who agreed with whom, the workings of the alleged scheme, what was done to effect the conspiracy, or the specifics of any agreement involving any of the Defendants. *See United States ex rel. Bates v. Dentsply Int'l, Inc.*, No. 12-7199, 2014 WL 4384503, at *9 (E.D. Pa. Sept. 4, 2014) ("relators have not stated a claim for conspiracy because they failed to identify any coconspirators in the second amended complaint and failed to allege an agreement").

RELATOR'S RETALIATION CLAIM UNDER THE FCA

The FCA also prohibits an employer from retaliating against employees who participate in investigating and prosecuting FCA violations. *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 185-86 (3d Cir. 2001) (citations omitted). Section 3730(h)(1) of the FCA provides:

> Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

31 U.S.C. § 3730(h)(1).

To prove retaliation under the FCA, a plaintiff must show (1) that he engaged in protected conduct, and (2) that he was discriminated against because of his protected conduct. *United States ex rel. Ascolese v. Shoemaker Constr. Co.*, 55 F.4th 188, 194

(3d Cir. 2022); *DiFiore v. CSL Behring, LLC*., 879 F. 3d 71, 76 (3d Cir. 2018). The PSH Defendants do not challenge whether the Relator engaged in protected conduct. Instead, they claim the Relator has failed to satisfy the second element by alleging that any retaliatory conduct on the part of the PSH Defendants rose to the level of adverse action as required by the FCA. Under the FCA, constructive discharge occurs when "the employer permitted conditions so unpleasant or difficult that a reasonable person would have felt compelled to resign." *Wiest v. Tyco Electronics Corp.*, 812 F.3d 319, 331 (3d Cir. 2016) (brackets omitted)**.**

Basically, Relator contends that because he did not receive satisfactory responses to his complaints about certain practices of the PSH Defendants, he believed he had no other option but to provide notice of his resignation on November 4, 2019. These complaints include receiving an insufficient response to his request to speak with PSH management about his concerns with the specimen policy. SAC at ¶¶ 439-454; Dr.Trina Abla, the Chief Quality Officer at St. Joseph's, encouraged a patient complaint against Relator *id*. at 455; a meeting with the hospital compliance department that was "delayed for several weeks," *id*. at ¶¶ 456-465; Relator received an invitation to an "Operational Issues" meeting without an explanation and when the contents of the meeting were finally explained to him after repeated inquiries, the meeting "disappeared off his calendar." *id*. at ¶¶ 466-474; he was asked to participate in a compliance meeting where he was assured that exemptions to the specimen policy would be put in place but ultimately were not. *id*. at ¶¶ 475-484; and that despite a compliance investigation into his concerns regarding the specimen policy, "no evidence was found to support his claims about the specimens." *Id*. at ¶¶ 485-504.

The Court finds as a matter of law that these conditions, when considered either singularly or collectively, fall well short of being "so unpleasant or difficult that a reasonable person would have felt compelled to resign." *Wiest*, 812 F. 3d at 331. Relator does not allege that he received any warning letters, negative performance reviews, a change to his medical duties or any type of performance improvement plan. *See, e.g. DiFiore* 879 F. 3d at 73-75, 79. Other than experiencing disagreements with his medical colleagues and his frustration with the results of investigations that he repeatedly advocated for, he does not allege that he had to work in a hostile environment. He admits himself that he was never under investigation. SAC at ¶ 502. Because Relator fails to show that he suffered an adverse employment action as a result of his actions, he has failed to satisfy the second element for a claim of retaliation under the FCA.

RELATOR'S STATE FALSE ACT CLAIMS

Relator's state false act claims against Cerner are similarly deficient.[4] Relator brings claims on behalf of 29 states for violation of each jurisdiction's respective state false claims act. Basically, Relator claims that the exact actions he claims violated the federal FCA also violate each State's respective false claims act. Because Relator does not allege that the state false claim statutes under which he asserts his state false act claims differ in any material way from the federal FCA, his state false act claims fail for the same reasons as his FCA claims. *See, e.g., Petratos*, 141 F. Supp. 3d at 322 (dismissing state law false claims act claims on same grounds as federal FCA claims

[4] See, 31 U.S.C. § 3732(b) ("The district courts shall have jurisdiction over any action brought under the laws of any State for the recovery of funds paid by a State or local government if the action arises from the same transaction or occurrence as an action brought under [the federal FCA].")

where the complaint did not differentiate the state false act claims from the federal FCA claims); *United States ex rel. Bergman v. Abbot Lab'ys*, 995 F. Supp. 2d 357, 377 (E.D. Pa. 2014) ("The above analysis of Relator's federal FCA claims under Rules 12(b)(6) and 9(b) also applies to Relator's state law claims."). [5]

In addition, Relator fails to allege that any purportedly improper activity by Cerner occurred in any of these states as opposed to the Commonwealth of Pennsylvania. Such an omission is fatal to his state false act claims. It is well-established that "[a] blanket pleading that alleges a 'nationwide' scheme in violation of the FCA but only provides specific examples of behavior violating the FCA in one jurisdiction fails to satisfy the particularity requirement of Rule 9(b) with respect to claims brought under the laws of other jurisdictions." *Travis*, 596 F. Supp. 3d at 543; *see United States ex rel. Forney v. Medtronic, Inc.*, No. 15-cv-6264, 2017 WL 2653568, at *5 (E.D. Pa. June 19, 2017) (dismissing claims brought under 29 analog state false claims statutes where relator stated that "Medtronic's alleged kickback scheme was 'nationwide' . . . and that Medtronic engaged in 'nationwide marketing' but failed to "reference any actual claims, services, providers, or conduct located outside of Pennsylvania"); *Foglia v. Renal Ventures Mgmt., LLC*, 830 F. Supp. 2d 8, 22 (D.N.J. 2011) (dismissing state claims where, among other things, the "amended complaint alleges no facts demonstrating that Defendant made false statements or misrepresentations, or concealed or failed to disclose information, in seeking to obtain an unauthorized payment or benefit under the

[5] Relator argues that the Texas Medicaid Fraud Prevention Act ("TMFPA") does not require the presentation of a "false claim" to establish materiality and encompasses a broader range of conduct than the FCA. However, Relator does not point to any allegations in the SAC that would constitute a violation of the TMFPA without satisfying the FCA's heightened pleading requirements. Additionally, the SAC does not include any allegations specific to Texas, so the TMFPA is invoked only to the extent that the TAC pleads a national scheme.

Texas Medicaid program"). Since Relator does not identify specific misconduct affecting multiple jurisdictions by Cerner, the state false claims act counts must be dismissed.

COMMON LAW STATE CLAIMS

Having dismissed the four federal claims against the Defendants and the 31 state false claims act causes of action for failure to state a claim, the court declines to exercise supplemental jurisdiction over Relator's remaining claims against the PSH Defendants under Pennsylvania law for retaliation for whistleblowing (Count XXXIV), defamation (Count XXXV), invasion of privacy (Count XXXVI) and breach of contract (Count XXXVII). 28 U.S.C. § 1367(c)(3). The "district court may decline to exercise supplemental jurisdiction over a claim if 'the district court has dismissed all claims over which it has original jurisdiction.'" *Elkadrawy v. Vanguard Grp.,* 584 F.3d 169, 174 (3d Cir.2009) (quoting 28 U.S.C. § 1367(c)(3)). "If it appears that the federal claim is subject to dismissal under Fed. R. Civ. P. 12(b)(6), then the court should ordinarily refrain from exercising jurisdiction in the absence of extraordinary circumstances." *Cito v. Bridgewater Twp. Police Dep't.,* 892 F.2d 23, 25–26 (3d Cir.1989). There are no extraordinary circumstances at bar that require the court to entertain the State law claims. Those claims are dismissed without prejudice to file in the appropriate state court.